MAY 0 3 2002

K014068

510(k) SUMMARY

Submitted by: W & H Dentalwerk Buermoos GmbH
Ignaz-Glaser-Strasse 53
A-5111 Buermoos
Austria

Contact person: Ralf Benda
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Date of Preparation: 06/12/2001

Device name: elcoMED SA-200 and elcoMED SA-200 C
Common name: Surgical unit for dental application
Classification name: Controller, foot, handpiece and cord

Predicate device: elcomed 100

Device Description:
elcoMED SA-200 and elcoMED SA-200 C consist of a small hand held motor, a foot control and a controller. The system components connect to each other via a proprietary coupling system.

Intended use:
Drive unit for surgical transmission instruments with coupling system according to DIN 13.940/ISO 3964 with the functions "mechanical drive" and "supply with coolant". It is indicated for use in dental, surgical procedures.

Technological Characteristics:
elcoMED SA-200 and elcoMED SA-200 C is the update of elcomed 100 and provides various changes of the design, a calibration function (only type elcoMED SA-200 C) to increase accuracy of torque measurement and a possibility to save data on a card.

Substantial equivalence:
elcoMED SA-200 and elcoMED SA-200 C and the predicate device share the same indication for use and similar technological characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 0 3 2002

Mr. Ralf Benda
W & H Dentalwerk Buermoos GmbH
53 Ignaz-Glazer-Strasse
Buermoos,
AUSTRIA 5111

Re: K014068
Trade/Device Name: elcoMed SA-200 115 (110-130 V), elcoMed SA 200 23 (220-240 V), elcoMed SA 200C 115 (100-130 V), elcoMed SA-200C 230 (220-240 V)
Regulation Number: 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: I
Product Code: EBW
Dated: March 5, 2002
Received: March 7, 2002

Dear Mr. Benda:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K014068

INDICATION FOR USE

Ver/ 3 - 4/24/96

Applicant: **W&H** Dentalwerk Buermoos GmbH

510(k) Number (if known): not known yet

Device Name: elcoMED SA-200 115 (100-130 V),elcoMED SA-200 230 (220-240 V), elcoMED SA-200C 115 (100-130 V), elcoMED SA-200C 230 (220-240 V)

Indications For Use:

The Indications are very widespread in the field of oral surgery.

A. Implant placement, including
    1. preparation of the osteotomy site
    2. bone reconturing, osteoplasty
B. Bone grafting
    1. Preparation of the donor site (for e.g. symphysis and ascending rames etc.)
    2. harvesting autogen living bone
    3. sinus elevation & grafting of alveolar sockets
C. Removal and sectioning of teeth ant teeth bone for e.g. impacted third molars and complicated extractions
D. Periodontal surgeries
    1. bone recontouring & alveoplasty around living teeth
    2. removal of exoslosis
E. Endodontic treatment
    1. Intracanal preparations using rotating NiTi-files

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K014068

Prescription Use ✓ OR Over-The-Counter-Use____
(Per 21 CFR 801.109) (Optional Format 1-2-96)